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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
ELLIS, SUEZU Y				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,031

Applicant(s)

MALCOLM ET AL.

Examiner

Suezu Ellis

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 6/7/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 7, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 1-6 are objected to because of the following informalities:

With respect to claims 1-6, claim language recites "the, or each, reservoir" or "the, or each, hole or opening". Examiner suggests the claim language be rephrased to "the at least one hole or opening" or "the at least one reservoir" for clarification purposes.

Appropriate correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification does not appear to adequately support utilizing a pore-forming excipient. Examiner notes the term implies the excipient forms pores, which is not described in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The term “pore-forming excipient” implies that the excipient forms pores. However the specification does not appear to support this. Examiner notes that in Example 3 of applicant’s specification, applicant includes a pore-forming excipient. However examiner further notes that the pores are already pre-made via the General Method of Manufacture for Examples 1-4 and this method discloses forming the pores

either by using projections that create the pores or by bore drilling. Therefore, the concept of utilizing an excipient for forms pores is considered to be non-enabling.

Claim 15 is considered to be non-enabling due to its dependency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7, 9-11 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 4, it is unclear what applicant means by the hole(s) or opening(s) is joined with an adjacent hole or opening to give a continuous opening in the form of a slit. As understood, a slit is one narrow hole. Therefore it is unclear as to how two holes create one continuous slit. Please clarify. Since the scope of the claim is so unclear, the claim will not be treated on the merits.

With respect to claim 7, claim language recites "the, or each, hole extends substantially radially, inwardly, outwardly, through the sheath". Since the sheath has holes in them, it is unclear what applicant means by the holes extending radially, inwardly, outwardly, through the sheath. Please clarify.

Claim 9 recites the limitation "said holes". There is insufficient antecedent basis for this limitation in the claim. Examiner notes that claim 2 recites "one or more holes or openings".

With respect to claim 10, it is unclear what applicant means by "a right circular cylinder". Please clarify.

With respect to claim 11, it is unclear if applicant means there are additional holes or slits provided in the sheath, or if applicant means the holes in claim 9 are provided through the sheath. Please clarify. If applicant means the holes are the same as that in claim 9, examiner notes that there is a lack of antecedent basis for the term "slits" in claim 11.

With respect to claim 14, it is unclear what applicant means by the term "pore-forming excipient". Does applicant mean the excipient forms pores? If so, it is unclear how this is performed. Please clarify. For examination purposes, claim language will be interpreted as a regular excipient.

With respect to claim 16, it is unclear if applicant means the sheath comprises an additional pharmacologically active agent or if it is the same pharmacologically active agent as recited in claim 1. Please clarify. If they are different, claim language needs to better differentiate the two agents. Proper antecedent basis is needed if they are the same.

Claim 15 is indefinite due to its dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 13, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham et al. (US 4,973,304).

With respect to claims 1, 17 and 18, Graham et al. discloses in Fig. 3, an intravaginal drug delivery device for administration into a vaginal environment, and a method of making the device, the device comprising at least one reservoir (hydrogel - 15), the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof (contraceptive) dispersed in a carrier system, and a sheath (tube - 11) discontinuously surrounding the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment (col. 6, lines 38-61; claim 1).

With respect to claims 2, 3 and 6, Graham et al. discloses in Fig. 3 the sheath has at least one hole (port -13) that extends through the sheath to the at least one reservoir so that at least part of the at least one reservoir is exposed to the vaginal environment and the hole(s) extends to the surface of the at least one reservoir, thereby extending through the sheath substantially normal to the reservoir surface.

With respect to claim 7, Graham et al. discloses in Fig. 3 the device is substantially circular in transverse cross-section and the hole(s) extends substantially radially, inwardly, outwardly, through the sheath.

With respect to claim 8, Graham et al. discloses in Fig. 3, the device having between one to thirty holes that are along the outer and inner circumference of the device.

With respect to claim 13, Graham et al. discloses the device being has a toroid shape (col. 6, line 38).

Claims 1, 2, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Drury (US 6,264,972)

With respect to claims 1, Drury discloses in Fig. 2, an intravaginal drug delivery device for administration into a vaginal environment, the device comprising at least one reservoir (14), the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof (col. 5, lines 28-58) dispersed in a carrier system, and a sheath (12) discontinuously surrounding the at least one reservoir so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment.

With respect to claim 2, Drury discloses in Fig. 2 the sheath has at least one hole that extends through the sheath to the at least one reservoir so that at least part of the at least one reservoir is exposed to the vaginal environment.

With respect to claims 9 and 10, Drury discloses in Fig. 2, the drug delivery device defines a circular cylinder and the holes are provided at each terminal end of the rod, and each base of the rod is partly or fully exposed to define the holes.

Claims 1-3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated Waterbury (US 3,521,637).

With respect to claim 1, Waterbury discloses in Fig. 2, an intravaginal drug delivery device for administration into a vaginal environment, the device comprising at

least one reservoir (5), the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof dispersed in a carrier system, and a sheath (3) discontinuously surrounding the at least one reservoir so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment (col. 3, lines 26-72).

With respect to claims 2 and 3, Waterbury discloses in Fig. 2, the sheath has at least one hole (17) that extends through the sheath to the at least one reservoir so that at least part of the at least one reservoir is exposed to the vaginal environment, and the at least one hole extends to the surface of the at least one reservoir and/or extends partially into the at least one reservoir.

With respect to claim 14, Waterbury discloses the inclusion of excipients in the reservoir (col. 5, line 63 – col. 6, line 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graham et al.

With respect to claim 5, Graham et al. addresses all the limitations of claims 1 and 2, however fails to expressly disclose the hole(s) having the claimed shape and

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diameter. However, Graham et al. does disclose the number and size of the hole(s) affect the rate of release of the active agent (col. 4, lines 17-25). It would have been obvious to one of ordinary skill to modify the shape and size of the hole(s) in order to attain the desired release rate of the active agent. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drury in view of Graham et al.

With respect to claims 11 and 12, Drury addresses all the limitations of claims 1, 2 and 9, however fails to expressly disclose the inclusion of additional holes or slits that radiates through the sheath. Graham et al. discloses a drug delivery device having holes on the ends and holes that radiate through the sheath (Fig. 1; col. 6, lines 65-57). It would have been obvious to one of ordinary skill in the art to modify the drug delivery device of Drury to include holes that radiate through the sheath in order to modify the release rate of the drug (col. 4, lines 17-25).

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drury in view of Waterbury.

With respect to claims 14 and 15, Drury addresses all the limitations of claim 1, however fails to expressly disclose the inclusion of an excipient. Waterbury discloses a drug delivery device that includes an excipient (stabilizer) in the reservoir (col. 5, line 63

– col. 6, line 2). It would have been obvious to one of ordinary skill to modify the drug delivery device to include excipients and to modify the type of excipient used in order to stabilize the desired active agent.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waterbury.

With respect to claim 15, Waterbury addresses all the limitations of claims 1 and 14, however fails to expressly disclose the type of excipient used. However, it would have been obvious to one of ordinary skill in the art to modify the type of excipient in order to stabilize the active agent (col. 6, lines 4-11). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waterbury in view of Fuchs et al. (US 4,136,162).

With respect to claim 16, Waterbury addresses all the limitations of claim 1, however fails to expressly disclose the sheath containing additional active agent. Fuchs et al. discloses a perforated film that contains an active agent, wherein the film is used to coat an intravaginal device (functionally equivalent to a sheath) (col. 4, lines 27-58). It would have been obvious to one of ordinary skill in the art to incorporate another

active agent into the sheath in order to provide a drug delivery device that delivers two active agents.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suez Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

*/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615*